

Drug Recall

DATE OF RECALL: July 28, 2023

DRUG NAME: Tydemy 3-0.03-0.451 mg and 0.451mg tablets

RECALLING FIRM: Lupin.

REASON FOR RECALL: This recall was issued due to an out of specification (“OOS”) result observed in inactive content (ascorbic acid) and impurity test at 12-month stability study specifically for lot (L200183).

FDA LINK: N/A

OTHER DETAILS: N/A

RECALLED PRODUCT:

Product Description	NDC Number	Lot Number	Expiration Date
*Tydemy 3-0.03-0.451 mg and 0.451 mg tablets 3 blisters of 28	68180-0904-73	L200183 L201560	01/2024 09/2024
Tydemy 3-0.03-0.451 mg and 0.451 mg tablets 1 blister of 28	68180-0904-71	L200183 L201560	01/2024 09/2024